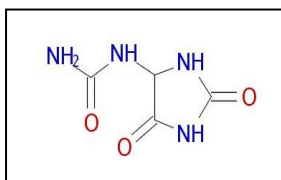


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INCI: **Allantoin**
N° CAS: 97-59-6
N°EINECS/ELINCS: 202-592-8

DESCRIPTION / DESCRIPTION:

Allantoïne C₄H₆N₄O₃. Poudre cristalline, blanche ou sensiblement blanche / *Allantoin C₄H₆N₄O₃. Crystalline powder, white or substantially white*

Matière première conforme à la Pharmacopée Européenne en vigueur (monographie 1288 : **ALLANTOINE**) & USP / *Raw material compliant to the European Pharmacopoeia in force (monography 1288: **ALLANTOIN**) & USP*

CARACTERISTIQUES GARANTIES / GUARANTEED SPECIFICATIONS:

CARACTERISTIQUES	SPECIFICATIONS	METHODES / METHODS
Aspect	White to off-white crystalline powder	IO-055
Identifications / <i>Identifications</i>	Conforme / <i>Compliant</i>	IO-056
pH (0.5% in H ₂ O at 20°C)	4-6	IO-206
Perte à la dessiccation / <i>Loss on drying</i>	≤ 0.1 %	IO-057
Cendres sulfuriques / <i>Sulfuric ashes</i>	≤ 0.1 %	IO-061
Pureté / <i>Assay</i>	≥ 99%	IO-207
Angle de rotation optique / <i>Optic rotation angle</i>	-0.10° - +0.10°	IO-060
Substances réductrices / <i>Reducing substances</i>	Conforms to Ph.Eur. & USP	IO-290
Acidité / <i>Acidity</i>	Conforms to Ph.Eur. & USP	IO-211
Substances apparentées / <i>Related substances</i>	Conforms to Ph.Eur. & USP	IO-210

Ces éléments seront repris sur nos BA / *these elements will be on our CoA*

CARACTERISTIQUES A TITRE D'INFORMATION / ADDITIONAL INFORMATION:

Point de fusion / *Melting point*: 225-236°C

Température de décomposition / *Decomposition temperature*: ~230°C

Masse molaire / *Molar mass*: 158.1 g/mol

Ce produit est conforme aux exigences Vegan / *This product is compliant with Vegan requirements*

ISO 16128

Natural Indice : 0 natural origin indice : 0

Organic Indice : 0 organic origin indice : 0

APPLICATIONS :

Fabrication de substances chimiques fines, formulation (mélange) de préparations et/ou reconditionnement (sauf alliages), services de santé, cosmétique / *Manufacture of fine chemical substances, formulation (mixture) of preparations and / or repackaging (except alloys), health services, cosmetic*

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CONDITIONNEMENT STANDARD / STANDARD PACKAGING :

Cartons de 25 kg / *Cardboards boxes of 25 kg*

Matière première non classifiée comme substance dangereuse / *Raw material not classified as dangerous substance*

A conserver au frais et au sec dans un emballage hermétiquement fermé et dans un lieu bien aéré / *Store in a cool, dry place in a tightly closed container and in a well-ventilated place*

Additives	Doesn't contain additives	
Allergen	This product doesn't contain food allergen (1169/2011) and cosmetics allergens (1223/2009 & 2023/1545)	
Animal Testing	This product has not been tested on animal	
BSE - Bovine Spongiform Encephalopathy	No material derived from BSE relevant animal species are used. This product synthetically manufactured is not of animal origin	
California Prop 65	This product Cas 97-59-6 is not listed in U.S. California The Proposition 65 List	
Carcinogenic, Mutagenic and Reprotoxic (CMR)	This product doesn't contain CMR (1272/2008 & 2023/1490)	
Composition	Allantoin 99.0 INCI : 100% Allantoin	
Cosmetic	Complying with cosmetic regulation 1223/2009/CEE and its amendments	
Cosmos / Ecocert	This product is produced by chemical synthesis – Not accepted by cosmos	
Danger	This product is not classified as dangerous in accordance with CLP or ADR	
Dioxane	This product is free of dioxane or 1,4 dioxine	
Ecolabel	Available on asking	
European Pharmacopeia	This product complies with European Pharmacopoeia and USP	
Food	Is not a food grade product	
Genetically Modified Organisms (GMO)	It is not used any raw material coming from any GMO in the production of the product	
Inventories	Cas 97-59-6 is listed in IECSC China TCSI Taiwan TSCA USA DSL Canada	ENCS Japan KECL Korea PICCS Philippines NZIoC New Zealand AIIIC Australia
Geographic origin (for plant)	Not concerned	
Glycol ether	This product is free of glycol ether	
Halal	Halal certificate is possible for this product	
Heavy Metals	Likely to be present, analyses every year: Heavy metals (as Lead) max 10ppm Cd (max 1 ppm), Pb (max 5 ppm), As (max 2 ppm),	Hg (max 1 ppm), Co (max 1 ppm), Ni (max 1ppm), Cr (max 1 ppm)
HS code	29332100	
Irradiation / ionization	This product is free of irradiation / ionization	
Kosher	This product is not Kosher certified	
Latex	Doesn't contain latex	
Manufacturing location	Spain	
Microbiological data	TAMC Max. 100 cfu/g TYMC Max. 100 cfu/g Pseudomonas aeruginos Negative in 1g Staphylococcus aureus Negative in 1g E. Coli Negative in 1g	

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	Candida Albicans Negative in 1g
Microplastics	In the production of Allantoine it is not used any microplastic material during manufacturing process. (2023/2055)
Nanomaterials	This product doesn't contain any nanomaterials (2011/696 & 1223/2009)
Nitrosamine	Not expected
Nutritional data	Not concerned
Origin	100% synthetic
PAH / PFAS	Not expected
Pesticide	This product doesn't contain pesticides
Phthalate	This product is free of phthalates
Preservative	This product is free of preservatives
Process	The production of Allantoin is carried out in a batch manufacturing process in which glyoxylic acid and urea react in an acidic medium to form Allantoin. Glyoxylic acid is dosed over an urea solution in acid medium. Once dosing is complete, digestion is carried out at temperature. After digestion is complete, it is cooled and transferred to a centrifuge buffer reactor, where solid/liquid separation is performed in a centrifuge, and washed with potable water. Finally, the wet product undergoes a drying process to remove moisture; micronized to reduce particle size and packaged as the final product.
REACH	Registered: 01-2119953242-43
Residual Solvents	This product is free of solvents (CPMP/ICH/283/95)
RSPO	This product doesn't contain palm derivate – not concerned
Shelf Life	8 years
Substances of Very High Concern (SVHC)	Not expected
Volatiles organic compounds (VOC)	Not expected (2010/79)

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Ce document annule et remplace tous documents techniques et réglementaires précédents / *This document cancels and replaces all technical and regulatory previous documents.*